Remarks

Amendments to the claims

Claims 1, 10, 18, and 28 have been amended to specify that the second domain of the bidomain peptide contains a polypeptide growth factor. Support for this amendment can be found in the specification at least at page 10, line 2 until page 11, line 3 and in claims 8, 15, 25 and 33 as originally filed. Claims 6, 8, 15, 23-25, and 31-33 have been canceled. Claims 7, 9, 16, 17, 26, 27, and 34 have been amended to refer to polypeptide growth factors.

Rejection Under 35 U.S.C. § 102

Claims 1-35 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,894,022 to Hubbell *et al.* ("the '022 patent"); U.S. Patent No. 6,607,740 to Hubbell *et al.* ("the '740 patent"); or U.S. Patent No. 6,331,422 to Hubbell *et al.* ("the '422 patent"). Applicants respectfully traverse the rejections in view of the '740 patent and the '422 patent. Applicants respectfully traverse the rejection over the '022 patent to the extent that it is applied to the claims as amended.

Legal Standard under 35 U.S.C. § 102(e)

For a reference to be available as prior art under 35 U.S.C. §102(e), the statue requires, in part, that "the invention was described in [...] a patent granted on an application for patent by another filed in the United States *before the invention by the applicant* for patent" 35 U.S.C. §102 (e) (emphasis added).

Priority claim for the pending application

The pending application is a continuation of U.S.S.N. 10/024,918 filed December 18, 2001, which is a continuation-in-part of U.S.S.N. 09/057,052, filed April 8, 1998 (now the '422 patent), which is a continuation of International Application No. PCT/US98/06617, filed April 2, 1998, which claims priority to U.S. Provisional Application Serial No. 60/042,143, filed April 3, 1997.

The '422 patent, the '740 patent and the pending application claim priority to the same applications

The '422 patent, the '740 patent and the pending application all claim priority to U.S.S.N. PCT/US98/06617, filed April 2, 1998 and to provisional application, U.S.S.N. 60/042,143 filed April 3, 1997. Additionally, both the '740 patent and the pending application claim priority to the '422 patent. The '422 patent and the '740 patent contain the same disclosure; and the pending application contains the disclosure of both the '422 patent and the '740 patent, along with additional examples and additional disclosures. Therefore, the disclosures in the '422 patent and the '740 patent are not available as prior art under 35 U.S.C. § 102(e) against the claims in the pending application.

The '022 patent

The '022 patent was filed May 1, 2000 and is a continuation-in-part application of U.S.S.N. 09/146,153 filed August 27, 1998 (now abandoned).

Claims 1-5, 10-14, 18-22, and 28-30 of the pending application

Support for claims 1-5, 10-14, 18-22, and 28-30 can be found in the pending application's priority application, U.S.S.N. 09/057,052, filed April 8, 1998. For example, support for claims 1 and 18 can be found at least at page 6, line 9, page 8, line 8 and page 9, lines 15-17; support for claims 2 and 11 can be found at least at page 2, line 22; support for claims 3, 12, 20, and 29 can be found at least at page 5, lines 20-21; support for claims 4, 5, 13, 14, 21, 22, and 30 can be found at least at page 9, lines 24-26; support for claim 10 can be found at least at page 5, lines 19-25 and page 6, lines 1-2 and 4-6; support for claim 19 can be found at least at page 5, line 20; and support for claim 28 can be found at least at page 6, line 9, page 8, line 8, page 9, lines 15-17 and page 11, lines 27-29 of U.S.S.N. 09/057,052.

U.S.S.N. 09/057,052 was filed before the earliest priority date for the '022 patent, i.e. August 27, 1998. Therefore, the '022 patent is not available as prior art under 35 U.S.C. § 102(e) against claims 1-5, 10-14, 18-22, and 28-30.

Claims 7, 9, 16, 17, 26, 27, 34 and 35 of the pending application

Claims 7, 9, 16, 17, 26, 27, 34 and 35 are dependent claims that further define the polypeptide growth factor in the bidomain protein or peptide.

The '022 patent discloses fusion proteins containing a crosslinking region, such as a Factor XIIIa substrate domain, and a polysaccharide-binding peptide domain (col. 5, lines 65-67). The polysaccharide-binding peptide domain typically contains a heparin-binding sequence, but does not contain the complete growth factor, or the bioactive fragment thereof (*see e.g.* col.

6, lines 4-5 and Table 2). Then heparin or another polysaccharide binds to the polysaccharide-binding peptide domain, *which in turn binds to a heparin binding protein*, such as a heparin binding growth factor (*see* col. 5, line 67- col. 6, line 2 and col. 7, lines 53-54). Thus the heparin binding growth factor is not located in one of the domains of the fusion protein. The '022 patent also describes polysaccharide-peptide chimeras, which contain a crosslinking region, such as a Factor XIIIa substrate domain, and a domain containing heparin or another polysaccharide, such as heparin sulfate (col. 9, lines 26-34). The heparin or another polysaccharide domain binds to a heparin binding protein, such as a heparin binding growth factor (*see* col. 7, lines 53-54). The '022 patent does not disclose forming a fusion peptide containing a transglutaminase substrate domain in one domain and a polypeptide growth factor in the second domain, where the growth factor is TGF-β1, BMP 2, $VEGF_{121}$, PDGF AB, L1Ig6, or a combination or bioactive fragments thereof, or VEGF, a growth factor from the TGF-β superfamily, PDGF, or IGF, as required by claims 7, 9, 16, 17, 26, 27, 34 and 35. Therefore claims 7, 9, 16, 17, 26, 27, 34 and 35 are novel in view of the '022 patent.

Double Patenting Rejections

Claims 1-35 were rejected under the judicially created doctrine of obviousness-type double patenting as being obvious in view claims 1-5 of the '022 patent. Claims 1-35 were rejected under the judicially created doctrine of obviousness-type double patenting as being obvious in view claims 1-18 of the '740 patent. Claims 1-35 were rejected under the judicially created doctrine of obviousness-type double patenting as being obvious in view claims 1-39 of

the '422 patent. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Legal Standard

M.P.E.P. §804 II(B)1 sets forth the conditions that must be met for claims to be rejected under the doctrine of obviousness-type double patenting. "Obviousness-type double patenting requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in ***a commonly owned*** patent, or ***a non-commonly owned patent but subject to a joint research agreement*** as set forth in 35 U.S.C. §103(c)(2) and (3), when the issuance of a second patent would provide unjustified extension of the term of the right to exclude granted by a patent." *Id.*, citing *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 58 U.S.P.Q.2d 1869 (Fed. Cir. 2001); *Ex parte Davis*, 56 U.S.P.Q.2d 1434, 1435-36 (Bd. Pat. App. & Inter. 2000), emphasis added. Thus in a rejection for obviousness-type double patenting, the pending application and the patent must either be owned by the same entity or subject to a joint research agreement.

The '022 patent

The '022 patent is jointly owned by Eidgenössische Technische Hochschule Zürich and Universität Zürich. The pending application is owned by California Institute of Technology. Thus the '022 patent and the pending application are not commonly owned. Additionally, the '022 patent and the pending application are not subject to a joint research agreement. Therefore

the rejection for obviousness-type double patenting over claims 1-5 of the '022 patent is an improper rejection.

As noted in the M.P.E.P., the '022 patent may be available as prior art for determinations under 35 U.S.C. §102(e). *See* M.P.E.P § 804, Chart II-B. However, such a rejection would be improper, as well, for at least the reasons presented above.

The '422 patent and the '740 patent

Applicants will submit a terminal disclaimer over the '422 patent and the '740 patent once the claims have been otherwise determined to be patentable.

Provisional Obviousness- type Double Patenting Rejections

Claims 1-35 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being obvious in view claims 1-34 of co-pending application U.S.S.N. 10/325,021 and claims 1-25 of co-pending application U.S.S.N. 10/323,046.

The office action refers to claims 1-34 of U.S.S.N. 10/325,501. However, this appears to be a typographical error as U.S.S.N. 10/325,501 is an issued patent, U.S. Patent No. 6,704,685, entitled "*Method And Device For Determining The Signal Running Time Between A Position Measuring System And A Processing Unit*". Therefore, Applicants have treated the provisional rejection as if it was made over claims 1-34 of co-pending application U.S.S.N. 10/325,021.

U.S.S.N. 10/325,021 and U.S.S.N. 10/323,046 are jointly owned by Eidgenössische Technische Hochschule Zürich and Universität Zürich. The pending application is owned by

California Institute of Technology. Thus U.S.S.N. 10/325,021 and U.S.S.N. 10/323,046 and the pending application are not commonly owned. Additionally, U.S.S.N. 10/325,021 and U.S.S.N. 10/323,046 and the pending application are not subject to a joint research agreement. Therefore the provisional rejections for obviousness-type double patenting over claims 1-34 of co-pending application U.S.S.N. 10/325,021 and claims 1-25 of co-pending application U.S.S.N. 10/323,046 are improper rejection.

Objections to the claims

The Examiner objected to the pending claims as being in conflict with the claims in copending applications U.S.S.N. 10/325,501 and U.S.S.N. 10/323,046. The pending claims, as amended, define different compositions and methods than the claims in U.S.S.N. 10/325,021 and U.S.S.N. 10/323,046.

Allowance of claims 1-5, 7, 9-14, 16-22, 26-30, 34, and 35, as amended, is respectfully solicited.

Respectfully submitted,

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